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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,454	01/05/2004	Jean-Paul Renard	045636-5058	9282

9629 7590 06/05/2007  
MORGAN LEWIS & BOCKIUS LLP  
1111 PENNSYLVANIA AVENUE NW  
WASHINGTON, DC 20004

EXAMINER
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BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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06/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,454	<b>Applicant(s)</b> RENARD ET AL.	
	<b>Examiner</b> Valarie Bertoglio	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The instant application has been transferred to Examiner Valarie Bertoglio, AU 1632.

This application was filed January 5, 2004, is a 371 national stage filing of PCT/FR00/02698, filed September 29, 2000, which claims benefit to foreign application 99/12287 filed October 1, 1999 in France.

Applicants' amendment filed 03/12/2007 has been received and entered. Claims 1-12 have been canceled. Claims 13, 16-18 and 24 have been amended. Claims 13-24 are pending and currently under examination.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on September 29, 2000. It is noted, however, that applicant has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

It is further noted that review of the preliminary examination report (IPER) of 01.10.1999 indicated that the priority document was not filed with the PCT. See feuille 1 PCT/IPEA/409 or page 12 of the document that includes the translation.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not identify the citizenship of each inventor.

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The country of citizenship is not listed for inventor Xavier Vignon.

***Specification***

The disclosure is objected to because of the following informalities: The measurement at page 6, line 27 does not contain a unit of measure.

Appropriate correction is required.

***Claim Objections***

The objection to claim 24 is withdrawn in light of Applicant's amendment to the claim.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically:

Claim 13 remains vague and unclear as to what is "reconstituted", and incomplete because while the preamble indicates a method for the reconstitution of an embryo the method steps only involve steps of obtaining a nuclear transfer unit. The preamble implies that the donor is transferred to recipient cytoplasm, and dependent claims set forth potential specific methodology (claims 19-22) however an embryo is not be formed by merely placing a donor nucleus into a cytoplasmic fraction. Further, the claim

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is unclear in the recitation of "controlled proteolysis" because what and how proteolysis is performed is not clearly set forth in the claim, nor in the present specification. Even in light of dependent claims that set forth specific enzymes to be used (claims 14 and 15), it is unclear what is being affected or to what extent, except the exclusion that histone proteins are not affected.

Applicant has added a step (ii) in attempt to overcome the aspect of the rejection that the claim is incomplete, however, the claim fails to require the formation of an embryo. What is obtained from the method as claimed, is an oocyte comprising a treated donor nucleus.

With respect to the term "controlled proteolysis", Applicant points to support at pages 5-6 of the specification. While it is agreed that the specification sets forth how to carry out such a step with a wide range of enzyme concentrations and treatment times, it fails to define what features of the nucleus define a "controlled proteolysis" such that one could define the metes and bounds of how much proteolysis is considered to be controlled. It is not clear based on the guidance in the specification how much proteolysis is too much or how much is not enough and thus would be considered outside the realm of "controlled". If Applicant wishes to rely on support in the specification for clarifying the metes and bounds of the claims, then parameters of treatment rather than descriptive limitations should be used. Claims 14-24 depend from claim 13.

The aspect of the rejection specific to claims 16 and 22 are withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United

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States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 13-17 under 35 U.S.C. 102(b) as being anticipate by Kraemer et al. (IDS reference) is withdrawn. Kraemer fails to teach transferring the swelled nucleus in to an oocyte.

The rejection of claims 13-15, 17 are rejected under 35 U.S.C. 102(b) as being anticipate by Aaronson et al. (JCB 62:746-754, 1974) is withdrawn. Aaronson fails to teach transferring the swelled nucleus in to an oocyte.

Claims 13-15, 17-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wangh et al. (US Patent 6,753,457 B2). The rejection is maintained for reasons of record set forth at page 6 of the office action dated 10/10/2006.

Applicant argues that Wang teaches additional method steps that are not required by the claims and that the claims are written with closed language "consisting of". This argument is not persuasive because the claim, in general, is written with open claim language comprising steps i) and ii). The closed claim language relates to steps a) and b). Thus, additional methodology taught by Wangh fits within the open structure of the claims as it contains steps i) and ii).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

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whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15, 17-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wangh et al. (US Patent 6,753,457 B2). The rejection is maintained for reasons of record set forth at pages 7-8 of the office action dated 10/10/2006.

Applicant argues that Wang teaches additional method steps that are not required by the claims and that the claims are written with closed language "consisting of". This argument is not persuasive because the claim, in general, is written with open claim language comprising steps I) and ii). The closed claim language relates to steps a) and b). Thus, additional methodology taught by Wangh fits within the open structure of the claims as it contains steps i) and ii).

Applicant also argues that one would not be motivated to modify Wangh *et al* to delete steps of treating the nuclei with an activating egg extract and contacting nuclei with CSF which are not claimed. In response, the open claim language of the claims is such that the claims encompass these additional steps. The "consisting of" language only pertains to the treatment of the diploid nucleus in steps a) or b). The claims fail to require omission of these steps as is indicated by Applicant's argument. Furthermore, by introducing a nucleus into an oocyte, the nucleus is coming in contact with these factors inherently present in the oocyte.

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*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Valarie Bertoglio  
Primary Examiner  
Art Unit 1632